



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 25

[Docket No. FDA-2013-N-1282]

National Environmental Policy Act; Environmental Assessments for Tobacco Products;

Categorical Exclusions

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: In accordance with the National Environmental Policy Act of 1969 (NEPA) and the Council on Environmental Quality (CEQ) Regulations Implementing NEPA (CEQ Regulations), the Food and Drug Administration (FDA) is proposing to revise its NEPA implementing regulations to provide categorical exclusions for certain actions related to substantial equivalence (SE) reports, SE exemption requests, and tobacco product applications, and the rescission (order withdrawing an order) or suspension of orders regarding the marketing of tobacco products under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). FDA is also proposing to amend its NEPA implementing regulations to include tobacco products, where appropriate, in light of its new authority under the Tobacco Control Act.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. FDA-2013-N-1282, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- Mail/Hand delivery/Courier (for paper, disk, or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2013-N-1282 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the "Comments" heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Gerie A. Voss, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 1-877-287-1373, gerie.voss@fda.hhs.gov.

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I. Background and Legal Authority

NEPA and the CEQ Regulations require each Federal Agency to assess, as an integral part of its decisionmaking process, the environmental impacts of any proposed Federal action to ascertain the environmental consequences of that action on the quality of the human environment

and to ensure that the interested and affected public is appropriately informed (42 U.S.C. 4332(2); 40 CFR 1506.6). The CEQ is responsible for the CEQ Regulations and for overseeing Federal efforts to comply with NEPA. Both FDA and CEQ have issued regulations governing Agency obligations and responsibilities under NEPA. The FDA regulations are included at 21 CFR part 25 and the CEQ regulations are at 40 CFR parts 1500 to 1508.

The CEQ regulations, which are binding on all Federal executive Agencies, establish procedures for implementing NEPA. Agencies may adopt procedures to supplement CEQ's regulations. In adopting NEPA-implementing procedures, Federal Agencies are directed by CEQ to reduce paperwork (40 CFR 1500.4 and 1500.2(b)) and to reduce delay (40 CFR 1500.5) by using several means, including the use of categorical exclusions. The CEQ regulations also state that Agencies shall continue to review their policies and procedures and, in consultation with CEQ, revise them as necessary to ensure full compliance with the purpose and provisions of NEPA (40 CFR 1507.3).

The FDA regulations state that for major Federal actions that may "significantly affect the quality of the human environment," FDA must prepare an environmental impact statement (EIS) (21 CFR 25.22; see also 40 CFR 1501.4). The term "significantly," as used in NEPA, requires considerations of both "context" (i.e., analyzed in several contexts) and "intensity" (i.e., severity of impact) (40 CFR 1508.27(a), (b)). If the action may have a significant environmental impact, FDA can either prepare an EIS or prepare an Environmental Assessment (EA). An EA provides sufficient information and analysis for FDA to determine whether to prepare an EIS or issue a finding of no significant impact (FONSI) (21 CFR 25.20; 40 CFR 1501.3). FDA is responsible for the scope and content of an EA and generally requires an applicant to prepare an EA and make necessary corrections to it (21 CFR 25.40(b)).

Categorically excluded actions refer to a category of actions that have been found not to individually or cumulatively have a significant effect on the quality of the human environment and which do not ordinarily require the preparation of an EA or EIS (40 CFR 1508.4). However, as required under 21 CFR 25.21 and 40 CFR 1508.4, FDA will require at least an EA for any specific action that ordinarily would be excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment.

If a submitter elects to request a categorical exclusion for a proposed action, a claim of categorical exclusion must be submitted in accordance with 21 CFR 25.15. Section 25.15 requires that the claim of categorical exclusion include: (1) A statement of compliance with the categorical exclusion criteria and (2) a statement that, to the submitter's knowledge, no extraordinary circumstances exist.

In November 2010, CEQ issued a final guidance on categorical exclusions including the process Agencies should use to establish new categorical exclusions. The guidance states that Agencies can establish new categorical exclusions to reduce paperwork and delay where the Agency has developed a record illustrating that the proposed categorical exclusion covers a category of action that, on the basis of past experience, does not normally have the potential to cause significant environmental effects (Ref. 1 at pp. 2 and 16). In addition, "[w]hen agencies acquire new responsibilities through legislation or administrative restructuring, they should propose new categorical exclusions after they, or other agencies, gain sufficient experience with the new activities to make a reasoned determination that any resulting environmental impacts are not significant" (Ref. 1 at p. 18).

FDA is proposing new categorical exclusions in accordance with NEPA, FDA, and CEQ regulations, and the CEQ November 2010 categorical exclusion guidance.

II. Overview of the Proposed Rule

Since FDA's NEPA policies and supplemental procedures were published in 1985 and prior to Congress giving FDA authority to regulate tobacco products in 2009, the Agency has prepared EAs for many Agency-initiated actions and has reviewed hundreds of EAs for a variety of industry requests for Agency action on foods, drugs, and medical devices for human consumption and use, and foods and drugs given to animals. In accordance with § 25.40(a) (21 CFR 25.40(a)), these EAs have focused on the potential environmental effects related to the use and disposal from use of the FDA-regulated articles. Based on FDA's experience reviewing EAs for actions involving foods, drugs, and medical devices for human consumption and use, and food and drugs given to animals, and its evaluation and knowledge of other relevant environmental science, FDA has determined that certain classes of actions related to tobacco products normally do not cause significant environmental effects and, therefore, should be added to the list of actions that are excluded from the requirement to prepare an EA or an EIS. In addition, FDA has gained sufficient experience from its responsibilities under the Tobacco Control Act to determine that certain actions on tobacco-related applications do not result in significant environmental impacts to the quality of the human environment. Accordingly, FDA is proposing several new categorical exclusions for tobacco product-related actions. See the "Statement of RADM David Ashley, Ph.D. and Hoshing Chang, Ph.D." (Ref. 2).

A. Classes of Tobacco Product-Related Actions Subject to Proposed Categorical Exclusions

FDA is proposing that the following classes of tobacco product-related actions qualify for categorical exclusions: (1) Issuance of an order finding a tobacco product substantially equivalent to a tobacco product commercially marketed in the United States as of February 15, 2007, under section 910(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act)

(21 U.S.C. 387j(a)(2)(B)); (2) issuance of an order finding a tobacco product not substantially equivalent under section 910(a) of the FD&C Act, an order under section 910(c) of the FD&C Act that a new tobacco product may not be introduced or delivered for introduction into interstate commerce, or an order under section 911 of the FD&C Act (21 U.S.C. 387k) that a modified risk tobacco product (MRTP) may not be introduced or delivered for introduction into interstate commerce (a modified risk tobacco product is any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products); (3) rescission (order withdrawing an order) or temporary suspension of an order authorizing the marketing of a new tobacco product under section 910 of the FD&C Act; (4) rescission of an order authorizing the marketing of a MRTP under section 911 of the FD&C Act; and (5) rescission of an order granting an exemption request under 21 CFR 1107.1.

For each proposed categorical exclusion, the environmental effect from the use and disposal from use of the tobacco product is negligible, if any, and would not individually or cumulatively have a significant effect on the quality of the human environment. Therefore, FDA believes that absent extraordinary circumstances, such actions should not require the preparation of any further analysis such as an EIS or an EA, which is intended to focus on "relevant environmental issues relating to the use and disposal from use of FDA-regulated articles" (§ 25.40(a)).

FDA also is proposing to amend several paragraphs of its existing environmental impact regulations in order to include tobacco products, where appropriate, in light of its new authority under the Tobacco Control Act.

1. SE Order Under Section 910(a)(2)(B) of the FD&C Act

FDA proposes that the Agency's issuance of an order finding a product to be substantially equivalent under section 910(a)(2)(B) of the FD&C Act qualifies for a categorical exclusion. Section 910(a)(2)(B) allows manufacturers of tobacco products that were first introduced or delivered for introduction into interstate commerce after February 15, 2007, and before March 22, 2011, and who submit a report by March 22, 2011, to continue to market the tobacco product unless the Agency issues an order that the tobacco product is not substantially equivalent and therefore must be removed from the market.

The estimated environmental effects that encompass all FDA-regulated tobacco products on the market, including products marketed after February 15, 2007, and before March 22, 2011, and grandfathered products (defined here as those products on the market as of February 15, 2007), are as follows:

a. Effects due to the manufacture of the tobacco products:

According to the 2011 Toxics Release Inventory (TRI) National Analysis, FDA estimates that 46,308 pounds of toxic chemicals (ammonia) were released to the land in the United States in 2011 without recycle and treatment; 3,702 pounds of toxic chemicals (including ammonia, nicotine and salts, and nitrate compounds) to the water; 719,451 pounds of toxic chemicals (including ammonia, chlorine, lead compounds, as well as nicotine and salts) to the air; 252,931 pounds of toxic chemicals (including ammonia, lead compounds, as well as nicotine and salts) recycled; and 1,563,193 pounds of toxic chemicals (including ammonia, nitrate compounds, as well as nicotine and salts) treated (Ref. 3). Compared to toxic waste released due to other manufacture activities estimated by the Environmental Protection Agency (EPA) using the same EPA database, the amount of waste released, recycled, and treated due to the manufacture of all

tobacco products on the market is a fraction of the total toxic waste released from and managed in industrial facilities in the United States (as reported in 2011 TRI National Analysis Report).

Table 1.--Release of Toxic Chemicals

	Chemicals in Pounds Released Due to Manufacture of Tobacco Products in 2011 (Derived from 2011 TRI National Analysis Report, EPA)		Total Toxic Released from and Managed in Industrial Facilities in the United States in 2011 (2011 TRI National Analysis Report, EPA) in Pounds
Land Total Release	Ammonia	46,308	1,255,558,266
Water Total Release	Ammonia	185	212,990,079
	Nicotine and Salts	285	
	Nitrate compounds	3,232	
	Subtotal	3,702	
Air Total Release	Ammonia	467,181	799,250,733
	Chlorine	294	
	Lead Compounds	38	
	Nicotine and Salts	251,938	
	Subtotal	719,451	
Total Recycled	Ammonia	775	8,601,489,350
	Lead Compounds	621	
	Nicotine and Salts	251,535	
	Subtotal	252,931	
Total Treated	Ammonia	30,385	7,397,857,287
	Nicotine and Salts	369,130	
	Nitrate compounds	1,163,678	
	Subtotal	1,563,193	

b. Effects due to use of the tobacco products:

As reported in the U.S. Department of Agriculture's 2007 Tobacco Outlook, the United States consumed 2.9 pounds of cigarettes per capita and 0.38 pounds of snuff per capita (adults age 18 and over) (Ref. 4). From 1996 to 2006, tobacco product consumption dropped by about 24 percent, chewing tobacco use decreased 41 percent, snuff use increased 23 percent, and cigarette smoking decreased 29 percent (Ref. 4).

The existing environmental impact resulting from cigarette and roll-your-own use is tobacco smoke, which is one of the causes of poor indoor air quality (Ref. 5). Environmental Tobacco Smoke (secondhand smoke) is classified as a Class A carcinogen by EPA (Ref. 6). Studies on outdoor tobacco smoke have shown that during periods of active smoking, peak and average outdoor tobacco smoke levels near smokers are equivalent to indoor tobacco smoke concentrations levels. However, outdoor tobacco smoke levels approached zero at distances greater than approximately 2 meters from a single cigarette and dropped almost instantly after smoking activity ceased (Ref. 7). The existing environmental impact resulting from use of smokeless tobacco products is not as substantial as that for cigarettes or roll-your-own tobacco. FDA expects that any new tobacco products that receive marketing authorization through the available pathways would have less or no more environmental impact than that of tobacco products currently on the market.

c. Effects due to the disposal from use of the tobacco products:

The existing environmental consequence resulting from disposal from use of cigarettes is from the discarded cigarette filters. Cigarette filters are primarily composed of cellulose acetate (Ref. 8) and may persist under normal environmental conditions for 18 months to 10 years (Ref. 9). As much as 766,571 metric tons of cigarette filters are discarded as litter worldwide each year (Ref. 10). Discarded cigarette filters are carried as runoff from streets to drains and rivers and, ultimately, to the ocean and its beaches and are found to be the most collected item in beach clean-ups and litter surveys (Ref. 10). Evidence has shown that cigarette butts are the most prevalent items discarded in urban areas (Ref. 11). Cigarette filters were found to be a point source for metal contamination litter, based on a study performed to assess the gradual release of multiple metals from the cigarette filter over the 34-day study period (Ref. 12). Scientists

evaluating the ecotoxicity of discarded cigarette filters also have shown the potential existing environmental consequences that result from disposal of cigarette filters. Scientists found that the solution made as a result of soaking smoked cigarette butts (smoked filter + tobacco) in water was toxic to both marine and fresh water fish used in the study (Ref. 13).

The existing environmental consequence resulting from disposal from use of smokeless tobacco is the impact on landfills. About 126 million pounds of smokeless tobacco were consumed in the United States in 2006, which resulted in an approximately equal amount of spent smokeless tobacco in the country's landfills (Ref. 14).¹

The Agency estimates that there are currently about 5,000 brands and subbrands of tobacco products on the market that are subject to FDA's tobacco product authorities. The majority of them are on the market under section 910(a)(2)(B) of the FD&C Act. The effects of keeping tobacco products on the market are individually and cumulatively trivial compared to the existing environmental effects due to toxic waste released from and managed in industrial facilities in the United States and the existing environmental effects due to the use and disposal from use of the tobacco products in the country. Therefore, the action should qualify for a categorical exclusion under proposed § 25.35(a).

2. Orders Under Sections 910(a), 910(c), and 911 of the FD&C Act

FDA proposes that the Agency's issuance of any of the following orders qualifies for a categorical exclusion: (1) An order finding a tobacco product not substantially equivalent under section 910(a) of the FD&C Act; (2) an order finding that a new tobacco product may not be introduced or delivered for introduction into interstate commerce under section 910(c) of the

¹ The consumption of smokeless tobacco in 2006 is estimated as follows: $225,662,922$ (U.S. population for age 18 years old and over in 2006) \times 0.38 (snuff consumption per capita 18 years and over in pounds, 2007) $+ 109,777,445$ (U.S. population for male age 18 years old and over in 2006) \times 0.37 (chewing tobacco consumption per capita male 18 years and over in pounds, 2007) $= 126,369,565$ pounds.

FD&C Act; or (3) an order finding that a modified risk tobacco product may not be introduced or delivered for introduction into interstate commerce under section 911. No use or disposal from use exists as a result of these actions. Generally, the effect of a denial for a new product application is to prevent the entry or continued entry of a product into the market. With regard to products that entered the market after February 15, 2007, and before March 22, 2011, and for which a report was submitted by March 22, 2011, the effect of a finding of not substantially equivalent would be to remove that product from the market. Such a removal would not result in the production or distribution of any substances and, therefore, would not result in the introduction of any substance into the environment. Therefore, FDA believes these actions would not individually or cumulatively have an effect on the quality of the human environment and should qualify for categorical exclusions under proposed § 25.35(b).

3. Rescission or Temporary Suspension of an Order Issued Under Section 910 of the FD&C Act

FDA proposes that the Agency's rescission or temporary suspension of an order authorizing the marketing of a new tobacco product under section 910 of the FD&C Act qualifies for a categorical exclusion. This action stops or suspends the use of a new tobacco product under section 910. The Agency is proposing that these rescissions or temporary suspensions of authorization, whether requested by industry or initiated by the Agency, be categorically excluded because these types of actions would not result in the production or distribution of any substances and, therefore, would not result in the introduction of any substance into the environment. Furthermore, assuming that users of the product continued to use tobacco, they would be expected to continue use by changing their use to products already on the market. These products would have been part of the baseline market that existed prior to passage of the Tobacco Control Act or would have already been subject to a categorical exclusion or an EA.

The discontinuation of use and disposal from use of the tobacco product would not individually or cumulatively have a significant impact on the quality of the human environment. Therefore, the action should qualify for a categorical exclusion under proposed § 25.35(c).

4. Rescission of an Order Issued Under Section 911 of the FD&C Act

FDA proposes that the Agency's rescission of an order authorizing the marketing of an MRTP under section 911 of the FD&C Act qualifies for a categorical exclusion. This action would prohibit a tobacco product manufacturer from the use of advertisements, labels, or labeling indicating that the product somehow reduces harm or the risk of tobacco-related diseases associated with other tobacco products. The Agency is proposing that these rescissions of authorization, whether requested by industry or initiated by the Agency, be categorically excluded because these types of actions would not result in the production or distribution of any substances and, therefore, would not result in the introduction of any substance into the environment. Accordingly, FDA believes the action would not individually or cumulatively have a significant effect on the quality of the human environment and should qualify for a categorical exclusion under proposed § 25.35(d).

5. Rescission of an Order Issued Under Section 905(j)(1)(A)(ii) of the FD&C Act and § 1107.1

FDA proposes that the Agency's rescission of an order authorizing the marketing of a new tobacco product under section 905(j)(1)(A)(ii) of the FD&C Act (21 U.S.C. 387e(j)(1)(A)(ii)) and § 1107.1 qualifies for a categorical exclusion. Section 1107.1 allows the Agency to rescind an exemption from the requirements relating to the demonstration of substantial equivalence where the tobacco product is modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if it finds that the exemption is not appropriate for the protection of public health (§ 1107.1(d)). The action

stops the use of a new tobacco product under these provisions. The Agency is proposing that these rescissions of authorization, whether requested by industry or initiated by the Agency, be categorically excluded because these types of actions would not result in the production or distribution of any substances and, therefore, would not result in the introduction of any substance into the environment. The discontinuation of use and disposal from use of the tobacco product would not individually or cumulatively have a significant effect on the quality of the human environment. Therefore, the action should qualify for a categorical exclusion under proposed § 25.35(e).

B. Extraordinary Circumstances for Tobacco Product-Related Actions

The current regulations state that FDA will require further analysis, at least an EA, for any specific action that ordinarily would be categorically excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment (§ 25.21). The regulations also state that examples of actions where extraordinary circumstances would preclude using a categorical exclusion include "[a]ctions for which available data establish that, at the expected level of exposure, there is the potential for serious harm to the environment" and "[a]ctions that adversely affect a species or the critical habitat of a [protected] species" (§ 25.21(a) and (b)).

These examples are applicable to tobacco products. If any tobacco product submission indicates that the action could result in the exposure of substances harmful to some biological mechanisms or systems in the environment or that the action may cause harm to a protected or endangered species, this would be considered an extraordinary circumstance that would warrant at least the preparation of an EA. FDA will continue to rely upon considerations of the intensity

and context as set out at 40 CFR 1508.27 for determining whether an extraordinary circumstance will result in the potential for a proposed action to significantly affect the environment.

C. Proposed Categorical Exclusions Would Benefit the Public Interest

FDA believes that this proposal would benefit FDA, regulated industry, and the public as a whole. The proposal would substantially reduce the numbers of EAs required to be submitted by industry and reviewed by FDA and, consequently, reduce the number of FONSIIs the Agency would be required to prepare for such applications. This would enable FDA to focus its environmental resources on situations likely to have an effect on the environment--a key goal of NEPA and CEQ (see 40 CFR 1500.4(b), 1500.5(k)). As CEQ noted in 2010, the "use of categorical exclusions can reduce paperwork and delay, so that EAs and EISs are targeted toward proposed actions that truly have the potential to cause significant environmental effects" (Ref. 1 at p. 16). The proposal also would allow tobacco product manufacturers to focus on other key portions of their applications, which is particularly necessary given that this industry has not been previously subject to Federal regulations. In addition, the proposal would benefit the tobacco product industry by alleviating otherwise necessary burdens given that "[g]enerally, FDA requires an applicant to prepare an EA and make necessary corrections to it" (21 CFR 25.40(b)). Furthermore, this rule would benefit the public health by allowing both FDA and industry to better focus their resources on other matters that could have a direct impact on the public health. Finally, § 25.21 provides a safeguard that allows the Agency to prepare or require industry to prepare an EA if there are extraordinary circumstances such that an action that ordinarily would be categorically excluded may significantly affect the quality of the human environment.

III. Description of the Proposed Rule

FDA proposes to amend Title 21 of the Code of Federal Regulations in order to:

- Clarify that part 25 applies to tobacco products subject to FDA's authority under Chapter IX of the FD&C Act (U.S.C. 387 through U.S.C. 387u); and
- Establish categorical exclusions specific to tobacco products.

Specifically, the proposed regulations would: (1) Amend § 25.15(a), (c), and (d) to indicate the availability of categorical exclusions under § 25.35; (2) amend § 25.20 by adding language to the introductory paragraph and adding paragraphs (p) and (q) to identify the tobacco-related actions that normally would require at least the preparation of an EA, unless the specific classes of actions are categorically excluded by the proposed exclusions in § 25.35; (3) revise the introductory paragraph of § 25.30 to reflect the new proposed categorical exclusions in § 25.35; (4) add § 25.35 to outline the categorical exclusions that apply solely to certain actions on tobacco product applications; (5) amend § 25.40(a) to indicate the availability of categorical exclusions under § 25.35; and (6) amend §§ 25.50(b) and 25.52(a), (b), and (c) to ensure that the public has an opportunity to participate in the development of environmental documents regarding tobacco products and that it receives notification of these documents.

A. General Procedures (§ 25.15)

The proposed rule would revise paragraphs (a), (c), and (d) of § 25.15 to add a reference to new proposed § 25.35, which would provide categorical exclusions for actions associated with various tobacco product submissions. Specifically, the addition to § 25.15(a) would explain that failure to submit an adequate EA with a tobacco application constitutes sufficient grounds for FDA to refuse to file or approve the application or petition, unless the action qualifies for a categorical exclusion under proposed § 25.35. The addition to § 25.15(c) would add the categorical exclusions under proposed § 25.35 to the classes of actions that qualify for

categorical exclusions. Finally, the addition to § 25.15(d) would provide that a person submitting a tobacco application or petition identified in proposed § 25.35 would not be required to submit an EA if the person's application states that: (1) The action requested qualifies for a categorical exclusion and (2) no extraordinary circumstances exist that would prevent the use of the categorical exclusion. For the purposes of tobacco products, the term "application" includes any application or submission to FDA (including SE reports and exemption requests) related to the marketing of tobacco products.

B. Actions Requiring Preparation of an Environmental Assessment (§ 25.20)

FDA proposes to revise § 25.20 to change the introductory paragraph to indicate the existence of tobacco-specific categorical exclusions under proposed § 25.35. In addition, FDA proposes to add to § 25.20 paragraphs (p) and (q) to state that the following Agency actions on tobacco applications require the preparation of an EA unless it is an action in a specific class that is categorically excluded: (1) Issuance of an order finding a tobacco product to be substantially equivalent under the FD&C Act, unless categorically excluded in § 25.35 and (2) issuance of an order authorizing the marketing of a new tobacco product under section 910 or an MRTP under section 911 of the FD&C Act, unless categorically excluded in § 25.35.

These revisions are necessary to make clear that certain types of actions on tobacco-related submissions could result in the requirement to prepare an EA, but manufacturers may be exempted from this requirement for certain classes of actions if the action qualifies for the use of a categorical exclusion.

C. General (§ 25.30)

The proposed rule would revise the introductory sentence to reflect the fact that we are proposing to add categorical exclusions in § 25.35. Therefore, those actions listed in § 25.30 and in §§ 25.30 through 25.35 would not ordinarily require the preparation of an EA or EIS.

D. Tobacco Product Applications (§ 25.35)

The proposed rule would add new § 25.35, which would provide additional categorical exclusions from the requirement to prepare at least an EA for certain actions on tobacco product submissions.

Specifically, proposed § 25.35(a) would provide for a categorical exclusion from preparing an EA for the issuance of an order finding that a product is substantially equivalent to a predicate product under section 910(a)(2)(B) of the FD&C Act.

Proposed § 25.35(b) would provide for a categorical exclusion regarding FDA's issuance of orders stating that: (1) A tobacco product is not substantially equivalent under section 910(a) of the FD&C Act; (2) a new tobacco product may not be introduced or delivered for introduction into interstate commerce under section 910(c) of the FD&C Act; or (3) a modified risk tobacco product may not be introduced or delivered into interstate commerce under section 911 of the FD&C Act.

Proposed § 25.35(c) would allow for a categorical exclusion where FDA rescinds or temporarily suspends an order authorizing the marketing of a new tobacco product under section 910 of the FD&C Act. Proposed § 25.35(d) would provide a categorical exclusion where FDA rescinds an order authorizing the marketing of a modified risk tobacco product under section 911 of the FD&C Act. Similarly, proposed § 25.35(e) would provide a categorical exclusion where FDA rescinds an order authorizing the marketing of a new tobacco product under section

905(j)(1)(A)(ii) of the FD&C Act and under § 1107.1. The term "new tobacco product" is defined in section 910(a)(1)(A) and (a)(1)(B) of the FD&C Act.

E. Environmental Assessments (§ 25.40)

The proposed rule would amend §25.40(a), which currently indicates that an EA shall be prepared for each action not categorically excluded in § 25.30, 25.31, 25.32, 25.33, or 25.34.

The proposed rule would delete "or 25.34" and replace with it with "25.34, or 25.35" to indicate the availability of additional categorical exclusions in proposed § 25.35.

F. General Information (§ 25.50)

The proposed rule would amend § 25.50(b), which relates to information protected from disclosure by law. By adding tobacco products to this regulation, FDA seeks to make clear that any environmental impact documentation regarding tobacco product applications (including SE reports and requests for exemptions from the requirements to demonstrate substantial equivalence) would not be released prior to issuance of an FDA order, unless the existence of such application has been made publicly available.

G. Environmental Impact Statements (§ 25.52)

Section 25.52 explains the process and requirements for public participation and notification regarding the preparation of an EIS for FDA-regulated products. Similar to other FDA-regulated products, FDA may determine that forthcoming actions involving tobacco products should require the preparation of an EIS. Therefore, the proposed rule would add "tobacco products" to paragraphs (a), (b), and (c) of § 25.52, where the regulation refers to actions on other FDA-regulated products that may require preparation of an EIS.

Specifically, the proposed rule would amend § 25.52(a) to explain that if an EIS is necessary for an action involving tobacco products, it would become available for review by the

public only at the time of the issuance of an order authorizing commercial marketing of the product in the United States. In addition, the proposed rule would amend § 25.52(b) to indicate that comments on the EIS may be submitted after the issuance of an order authorizing commercial marketing of the tobacco product in the United States and that these comments can form the basis for beginning the process of rescinding the marketing authorization. The proposed rule also would amend § 25.52(c) to state that where the existence of an application for a tobacco product has been disclosed before the Agency action, FDA will involve the public in preparing an EA or an EIS while continuing to adhere to the Agency's disclosure regulations with regard to confidential commercial information that has not been disclosed.

Further, the proposed rule would amend § 25.52(a) and (b) to add references to "market authorizations." As currently written, § 25.52(a) and (b) do not identify all the types of actions that could be taken with regard to tobacco products, including market authorizations. Not only can FDA engage in review and assessment of investigations with respect to tobacco products, but the Agency also may provide market authorizations in response to applications regarding tobacco products (see, e.g., section 911(g)(1) of the FD&C Act).

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship

between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

VI. Environmental Impact

The proposed amendment of the FDA NEPA Regulations (21 CFR part 25) concerns NEPA documentation for certain actions on tobacco product submission. CEQ does not direct Agencies to prepare a NEPA analysis or document before establishing Agency procedures that supplement the CEQ regulations for implementing NEPA. Agencies are required to adopt NEPA procedures that establish specific criteria for, and identification of, three classes of actions: Those that require preparation of an EIS; those that require preparation of an EA; and those that are categorically excluded from further NEPA review (40 CFR 1507.3(b)). Categorical exclusions are one part of those Agency procedures, and therefore establishing categorical exclusions does not require preparation of a NEPA analysis or document. Agency NEPA procedures, such as the FDA NEPA regulations assist FDA in the fulfillment of Agency responsibilities under NEPA, but are not FDA's final determination of what level of NEPA analysis is required for a particular proposed action on a tobacco product submission. The requirements for establishing Agency NEPA procedures are set forth at 40 CFR 1505.1 and 1507.3. Furthermore, the Agency has also determined under 21 CFR 25.30(h) that this rulemaking does not individually or cumulatively have a significant effect on the quality of the human environment.

VII. Analysis of Impacts

The analysis of economic impacts is available as Reference 15 in Docket No. FDA-2013-N-1282 and at

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>.

VIII. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). As noted previously, if you have comments on specific provisions of the proposed regulation, we request that you identify these provisions in your comments. In addition, if you have concerns that would be addressed by alternative text for the regulation, we request that you provide this alternative text in your comments. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

IX. References

The following references have been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified all the Web site addresses in this reference section, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.)

1. Council on Environmental Quality, "Final Guidance for Federal Departments and Agencies on Establishing, Applying, and Revising Categorical

Exclusions Under the National Environmental Policy Act," 76 FR 3843, January 21, 2011.

2. Statement of RADM David Ashley, Ph.D. and Hoshing Chang, Ph.D., "Impact of Tobacco Products on the Environment."

3. 2011 Toxic Release Inventory (TRI) National Analysis. Available at http://www.epa.gov/tri/tridata/tri11/nationalanalysis/overview/2011_TRI_NA_Overview.pdf.

4. U.S. Department of Agriculture. "Tobacco Outlook Report," Economic Research Service, 2007. <http://usda01.library.cornell.edu/usda/ers/TBS//2000s/2007/TBS-10-24-2007.pdf>. Accessed on August 29, 2012.

5. Poor Air Quality, available at <http://www.epa.gov/iaq/pubs/insidestory.html>.

6. U.S. Environmental Protection Agency, "Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders," EPA/600/6-90/006F, December 1992.

7. Klepeis, N.E., W.R. Ott, and P. Switzer, "Real-Time Measurement of Outdoor Tobacco Smoke Particles," Journal of the Air & Waste Management Association, 57:5, 522-534, 2007.

8. U.S. Department of Health and Human Services, "Reducing the Health Consequences of Smoking: 25 Years of Progress." A Report of the Surgeon General, 1989. Rockville, MD: Public Health Service, Centers for Disease Control, Office on Smoking and Health, 1989. (DHHS Publication No (CDC) 89-8411.)

9. Ach, A. Biodegradable Plastics Based on Cellulose Acetate. Journal of Macromolecular Science: Pure and Applied Chemistry. A30:733-740, 1993.
10. Smith, E.A. and T.E. Novotny, "Whose Butt Is It? Tobacco Industry Research About Smokers and Cigarette Butt Waste." Tobacco Control, 20:I2-I9, 2011. DOI: 10.1136/tc.2010.040105.
11. Department for the Environment, Food and Rural Affairs of the U.K. "Preventing Cigarette Litter in England: Guidelines for Local Authorities," DEFRA 2007.
12. Moerman, J.W. and G.E. Potts, "Analysis of Metals Leached From Smoked Cigarette Litter." Tobacco Control, 20:I30-I35, 2011. DOI: 10.1136/tc.2010.040196.
13. Slaughter, E.; R.M. Gersberg, K. Watanabe, et al., "Toxicity of Cigarette Butts, and Their Chemical Components, to Marine and Freshwater Fish," Tobacco Control, 20: I25-I29 2011.
14. United States Census Bureau, Vintage 2006: National Tables, available at http://www.census.gov/popest/data/historical/2000s/vintage_2006/index.html; accessed October 20, 2012.
15. Preliminary Regulatory Impact Analysis.

List of Subjects in 21 CFR Part 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR Chapter I be amended as follows:

PART 25--ENVIRONMENTAL IMPACT CONSIDERATIONS

1. The authority citation for part 25 continues to read as follows:

Authority: 21 U.S.C. 321-393; 42 U.S.C. 262, 263b-264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500-1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531-533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123-124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356-360.

§ 25.15 [Amended]

2. Amend § 25.15 as follows:

- a. Remove from paragraph (a) "or 25.34," and add in its place "25.34, or 25.35,";
- b. Remove from paragraph (c) "or 25.34" and add in its place "25.34, or 25.35"; and
- c. Remove from paragraph (d) "or 25.34," and add in its place "25.34, or 25.35,".

3. Amend § 25.20 by revising the introductory text and by adding paragraphs (p) and (q) to read as follows:

§ 25.20 Actions requiring preparation of an environmental assessment.

Any proposed action of a type specified in this section ordinarily requires at least the preparation of an EA, unless it is an action in a specific class that qualifies for exclusion under §§ 25.30, 25.31, 25.32, 25.33, 25.34, or 25.35:

* * * * *

(p) Issuance of an order finding a tobacco product substantially equivalent under Federal Food, Drug, and Cosmetic Act, unless categorically excluded under § 25.35.

(q) Issuance of an order authorizing marketing of a new tobacco product under section 910 of the Federal Food, Drug, and Cosmetic Act or an order authorizing marketing of a modified risk tobacco product under section 911 of the Federal Food, Drug, and Cosmetic Act, unless categorically excluded under § 25.35.

4. Amend the introductory text of § 25.30 by removing "25.34" and adding in its place "25.35".

5. Add new § 25.35 to subpart C to read as follows:

§ 25.35 Tobacco product applications.

The classes of actions listed in this section are categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS:

(a) Issuance of an order finding a tobacco product substantially equivalent under section 910(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act;

(b) Issuance of an order finding a tobacco product not substantially equivalent under section 910(a) of the Federal Food, Drug, and Cosmetic Act, issuance of an order under section 910(c) of the Federal Food, Drug, and Cosmetic Act that a new tobacco product may not be introduced or delivered for introduction into interstate commerce, or issuance of an order under section 911 of the Federal Food, Drug, and Cosmetic Act that a modified risk tobacco product may not be introduced or delivered for introduction into interstate commerce;

(c) Rescission or temporary suspension of an order authorizing the marketing of a new tobacco product under section 910 of the Federal Food, Drug, and Cosmetic Act;

(d) Rescission of an order authorizing the marketing of a modified risk tobacco product under section 911 of the Federal Food, Drug, and Cosmetic Act; and

(e) Rescission of an order granting an exemption request under § 1107.1 of this chapter.

6. Amend § 25.40 by removing from paragraph (a) "or § 25.34" and adding in its place, "§ 25.34, or § 25.35."

7. Amend § 25.50 by revising the first, third, fourth, and fifth sentences of paragraph (b) to read as follows:

§ 25.50 General information.

* * * * *

(b) Many FDA actions involving investigations, review, and approval or market authorization of applications, and premarket notifications for human drugs, animal drugs, biologic products, devices, and tobacco products are protected from disclosure under the Trade Secret Act, 18 U.S.C. 1905, and section 301(j) of the Federal Food, Drug, and Cosmetic Act. *

* * Even the existence of applications for human drugs, animal drugs, biologic products, devices, and tobacco products is protected from disclosure under these regulations. Therefore, unless the existence of applications for human drugs, animal drugs, biologic products, tobacco products, or premarket notification for devices has been made publicly available, the release of the environmental document before approval or authorization of human drugs, animal drugs, biologic products, devices and tobacco products is inconsistent with statutory requirements imposed on FDA. Appropriate environmental documents, comments, and responses will be included in the administrative record to the extent allowed by applicable laws.

8. Amend § 25.52 by revising the first sentence of paragraph (a), and paragraphs (b) and (c) to read as follows:

§ 25.52 Environmental impact statements.

(a) If FDA determines that an EIS is necessary for an action involving investigations, approvals, or market authorizations for drugs, animal drugs, biologic products, devices, or tobacco products, an EIS will be prepared but will become available only at the time of the approval or market authorization of the product. * * *

(b) Comments on the EIS may be submitted after the approval or market authorization of the drug, animal drug, biologic product, device, or tobacco product. Those comments can form

the basis for the Agency to consider beginning an action to withdraw the approval or market authorization of applications for a drug, animal drug, biologic product, or tobacco product, or to withdraw premarket notifications or premarket approval applications for devices.

(c) In those cases where the existence of applications and premarket notifications for drugs, animal drugs, biologic products, devices, or tobacco products has already been disclosed before the Agency approves the action, the Agency will ensure appropriate public involvement consistent with 40 CFR 1506.6 and part 1503 in preparing and implementing the NEPA procedures related to preparing EIS's while following its own disclosure requirements including those listed in part 20 and §§ 312.130(b), 314.430(d), 514.11(d), 514.12(b), 601.51(d), 807.95(e), 812.38(b), and 814.9(d) of this chapter.

* * * * *

Dated: January 15, 2014.

Leslie Kux,

Assistant Commissioner for Policy.